

### **REMARKS**

Claims 1-11 and 13-74 are pending in the present application. Those claims are set forth in the listing of claims included with the Response filed on October 14, 2008.

Claims 1-11, 13, 27-42 and 63-74 were examined in the Office Action dated December 30, 2008. Claims 14-26 and 43-62 have been withdrawn from consideration after a restriction requirement.

A Request to Correct Inventorship is also being submitted with this response. Fewer than all of the currently named inventors are the actual inventors of the invention being claimed in the nonprovisional application, so the Request is being filed to delete the names of the persons who are not inventors of the invention being claimed. A new Application Data Sheet is also being submitted.

A Declaration Under Rule 1.131 is also being submitted with this response. The Declaration is by the actual inventors of the invention being claimed in the present application.

#### **Claim Rejections - 35 USC § 112**

Claims 27-42 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office Action stated that there is no disclosure in the specification that excludes use of glutaraldehyde as sterilizing agent, and that the disclosure pointed out by the applicant merely points out a disadvantage but does not exclude use of glutaraldehyde.

In order to expedite prosecution of the present application, Applicants have amended claim 27 to remove the exclusion of glutaraldehyde, which formed the basis of the rejection. The present amendment should not be viewed as an indication that the Applicants agree with or acquiesce in the rejection.

#### **Claim Rejections - 35 USC § 102**

Claims 27-30, 34-35, 39 and 41 were rejected under 35 U.S.C. 102(e) as being unpatentable over Ogle (20030229394). The Office Action stated that Ogle '394

discloses a process for treating an implant prior to implantation, where crosslinking is disclosed to eliminate antigens and to eliminate hyper-acute immune response. The Office Action asserted that the use of glutaraldehyde also would sterilize the tissue as glutaraldehyde is a known sterilant as well as a fixative/crosslinking agent.

Applicants are submitting a Declaration Under Rule 1.131 which establishes that the claimed process was conceived and reduced to practice in the United States prior to the filing date of Ogle '394, which was June 6, 2002. Accordingly Ogle '394 is not prior art to the present application under 35 U.S.C. § 102(e). Therefore, the rejection of those claims should be withdrawn.

#### **Claim Rejections - 35 USC § 103**

Claims 38 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ogle (2003/0229394) in view of Wolfinbarger (6,024,735). Claims 1-5, 7-11, 13, 27, 31-42, 63-68 and 70-74 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Ogle US 20030229394). Claims 6 and 69 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mills '037 in view of Ogle '394 and further in view of Wolfinbarger '735. Claim 64 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Ogle '394 in view of Wolfinbarger '735.

The various rejections under 35 U.S.C. § 103(a) all rely upon Ogle '394 as prior art. As noted above, Applicants are submitting a Declaration Under Rule 1.131 which establishes that the claimed process was conceived and reduced to practice in the United States prior to the June 6, 2002 filing date of Ogle '394. Since Ogle '394 does not qualify as prior art, the rejection of claims for obviousness based on Ogle '394 is unsustainable and should be withdrawn.

#### **Petition for a Three Month Extension of Time**

Applicants hereby petition for a three-month extension of time in which to respond to the Office Action of December 30, 2008. The Commissioner is authorized to charge

the requisite extension fee of \$1,110.00, and any necessary fees for this submission, to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

**CONCLUSION**

For the foregoing reasons, Applicants submit that claims 1-11, 13, 27-42 and 63-74 are in condition for allowance. Applicants also request rejoinder and allowance of claims 14-26 and 43-62.

The Examiner is invited to telephone Applicants' representative to discuss any questions or if Applicants' representative may be of any assistance to the Examiner in the reconsideration and allowance of this case.

The Commissioner is authorized to charge any necessary fees to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

Respectfully submitted,

Dated: June 30, 2009



Michael B. Harlin  
Reg. No. 43,658  
Attorney for Applicants

MCANDREWS, HELD & MALLOY, LTD.  
500 West Madison Street, 34<sup>th</sup> Floor  
Chicago, IL 60661  
Telephone: (312) 775-8000  
Facsimile: (312) 775-8100